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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,892	10/20/2003	N. Leigh Anderson	41119B	3893

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EXAMINER	
EPPERSON, JON D	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/689,892	ANDERSON, N. LEIGH	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, 10-18, drawn to a microarray having immobilized thereon a plurality of oligonucleotides, classified variously in class 977, subclass 789.

II. Claims 3-6, 33-34, drawn to a recombinant microorganism capable of expressing a receptor on its surface or a plurality of such recombinant microorganisms, classified variously in class 435, subclass 69.1.

III. Claims 7-9, 32, drawn to a nucleic acid labeled receptor or a plurality of such receptors, classified variously in class 536, subclass 23.1 (when the receptor is the nucleic acid), class 435, DIG 16 (when the receptor is a protein), etc. depending on the nature of the receptor.

IV. Claims 19-31, drawn to a method for determining the presence of a ligand in a sample of mixture of different ligands using the microorganism of claim 3 or the receptor of claim 7, classified variously in class 435, subclass 6.

V. Claims 35-39, drawn to a method for fractionating a mixture of recombinant microorganisms, classified variously in class 536, subclass 23.1 (when the receptor is the nucleic acid), class 435, DIG 16 (when the receptor is a protein), etc. depending on the nature of the receptor.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and III are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect. For example, Group III requires a receptor, that is not required by Group I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

4. Inventions II and III are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have a materially different design, mode of operation, function, or effect. For example, Group III requires a nucleic acid to be "chemically bound" such as a polypeptide nucleic acid construct, which is not required for Group II. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Alternatively, Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that

the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because Group III is broader than Group II in that encompasses both "physical" and "covalent" association. The subcombination has separate utility such as expression of genes including synergistic expression wherein heavy and light antibody chains can be bound in close proximity such that they interact with one another to form functional antibodies.

6. Inventions I-III and IV/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, (1) the process for using the product as claimed can be practiced with another materially different product (e.g., the product of Groups II or III). In addition, the product as claimed can be sued in a materially different process of using that product (e.g., Groups IV or V drawn to screening and/or fractionating/chromatograph).

7. Inventions IV and V are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed result in a different effect (e.g., screening versus purifying). Furthermore, the inventions as claimed do not encompass

overlapping subject matter and there is nothing of record to show them to be obvious variants.

8. These inventions have acquired a separate status in the art as shown by their different classification (e.g., see paragraph 1) and/or divergent subject matter (e.g., see paragraphs 3). The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-V. Election is required as follows.

10. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of solid phase substrate (e.g., see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of solid phase substrate for "immobilization" (e.g., glass, see specification, paragraph 51). Applicants must also indicate whether said substrate particles are "discrete" (e.g., see specification, paragraph 41 wherein beads are disclosed). In addition, Applicants must indicate whether said beads, if elected, are ferromagnetic.

Subgroup 2: Species of nucleic acid sequence tag (e.g., see claims 17 and 18)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid sequence tag (e.g., antibody gene, cellular gene, etc.).

11. If applicant elects the invention of Group II, applicant is required to elect from the

following patentably distinct species. Claim 3 is generic.

Subgroup 1: Species of solid phase substrate if present (e.g., see claim 33)

Applicant must elect, for the purposes of search, a ***single species*** of solid phase substrate for "immobilization" (e.g., glass, see specification, paragraph 51). Applicants must also indicate whether said substrate particles are "discrete" (e.g., see specification, paragraph 41 wherein beads are disclosed). In addition, Applicants must indicate whether said beads, if elected, are ferromagnetic.

Subgroup 2: Species of recombinant microorganism (e.g., see claim 3)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant microorganism (e.g., phage).

Subgroup 3: Species of nucleic acid sequence tag (e.g., see claims 5 and 6)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid sequence tag (e.g., antibody gene, cellular gene, etc.).

Subgroup 4: Species of ligand/receptor (e.g., see claim 33)

Applicant must elect, for the purposes of search, a ***single species*** of ligand/receptor (e.g., avidin/biotin, see specification paragraph 48).

12. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 7 is generic.

Subgroup 1: Species of solid phase substrate (e.g., see claim 32)

Applicant must elect, for the purposes of search, a ***single species*** of solid phase substrate for "immobilization" (e.g., glass, see specification, paragraph 51). Applicants must also indicate whether said substrate particles are "discrete" (e.g., see specification, paragraph 41 wherein beads are disclosed). In addition, Applicants must indicate whether said beads, if elected, are ferromagnetic.

Subgroup 2: Species of nucleic acid sequence tag (e.g., see claims 9)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid sequence tag (e.g., antibody gene, cellular gene, etc.).

Subgroup 3: Species of ligand/receptor (e.g., see claim 8)

Applicant must elect, for the purposes of search, a ***single species*** of ligand/receptor (e.g., avidin/biotin, see specification paragraph 48).

13. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 19 is generic.

Subgroup 1: Species of solid phase substrate (e.g., see claim 19)

Applicant must elect, for the purposes of search, a ***single species*** of solid phase substrate for "immobilization" (e.g., glass, see specification, paragraph 51). Applicants must also indicate whether said substrate particles are "discrete" (e.g., see specification, paragraph 41 wherein beads are disclosed). In addition, Applicants must indicate whether said beads, if elected, are ferromagnetic.

Subgroup 2: Species of recombinant microorganism (e.g., see claim 19)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant microorganism (e.g., phage, yeast, etc.).

Subgroup 3: Species of nucleic acid sequence tag (e.g., see claim 28)

Applicant must elect, for the purposes of search, a ***single species*** of nucleic acid sequence tag (e.g., antibody gene, cellular gene, etc.).

Subgroup 4: Species of ligand (e.g., see claim 28)

Applicant must elect, for the purposes of search, a ***single species*** of ligand (e.g., protein). In addition, Applicants must indicate with specificity the type of ligand in addition to the claims (e.g., antibody).

Subgroup 5: Species of receptor (e.g., see claim 28)

Applicant must elect, for the purposes of search, a ***single species*** of receptor (e.g., antibody). In addition, Applicants must indicate where this receptor is located (e.g., surface of a virus) and describe the entity to which it is attached (e.g., phage particle).

14. If applicant elects the invention of Group V, applicant is required to elect from the following patentably distinct species. Claim 35 is generic.

Subgroup 1: Species of solid phase substrate (e.g., see claim 35)

Applicant must elect, for the purposes of search, a ***single species*** of solid phase substrate for "immobilization" (e.g., glass, see specification, paragraph 51). Applicants must also indicate whether said substrate particles are "discrete" (e.g., see specification, paragraph 41 wherein beads are disclosed). In addition, Applicants must indicate whether said beads, if elected, are ferromagnetic.

Subgroup 2: Species of recombinant microorganism (e.g., see claim 35)

Applicant must elect, for the purposes of search, a ***single species*** of recombinant microorganism (e.g., phage, yeast, etc.).

Subgroup 3: Species of ligand/receptor (e.g., see claim 37)

Applicant must elect, for the purposes of search, a ***single species*** of ligand/receptor (e.g., avidin/biotin. Please elect a specific ligand/receptor (e.g., avidin/biotin) as a opposed to a class of ligands/receptors (e.g., protein).

15. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 18 and 19 below).

16. The species are distinct if the species as claimed do not overlap in scope, i.e., are mutually exclusive; the species as claimed are not obvious variants; and the species as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.04(f). Here, the species of support encompass virtually an unlimited number of materials (e.g., glass plates, polystyrene beads, etc.), which can be separately classified and do not share any core structure. Likewise, the recombinant microorganism also encompass an enormous number of variants that can be separately classified (e.g., phage, yeast, etc.). Moreover, the species of ligand/receptor encompass a tremendous number of variants and can be separate classified depending on the nature of the molecules used

(e.g., protein, nucleic acid). Furthermore, all of these distinct species would require a separate non-coextensive search in the literature. For example, proteins might be found in a journal like the journal of protein science whereas nucleic acids might be found in a journal like RNA. Therefore, the claims encompass numerous patentable distinct species as exemplified above, which does create an undue search burden for the office

17. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

19. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of

claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

22. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

24. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
April 2, 2007

JON EPPERSON
PRIMARY EXAMINER